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Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DECLARATION OF ELIZABETH C. HELM IN SUPPORT OF DEFENDANTS' MOTION TO SEAL DOCUMENTS FILED IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT REGARDING PREEMPTION

(Assigned to the Honorable David G. Campbell)

I, Elizabeth C. ("Kate") Helm, declare under penalty of perjury that the following is true and correct:

1. I am over the age of 21 and am a resident of the state of Georgia. I have personal knowledge of the facts and circumstances set forth in this Declaration and, if

called upon to do so, I could and would competently testify thereto.

2. I am a lawyer licensed to practice in the State of Georgia. I am a partner at Nelson Mullins Riley & Scarborough, LLP, and I am one of the lawyers representing C.R. Bard, Inc. and Bard Peripheral Vascular (collectively "Bard") in the Bard IVC Filters Products Liability Litigation.

3. I am the lawyer for Bard who has participated in the meet and confer process with plaintiffs' counsel regarding plaintiffs' challenges to the Bard privilege logs and in the redactions of the documents now filed redacted.

4. During the numerous meet-and-confer sessions regarding Bard's Motion to Seal documents filed in support of Bard's Motion for Summary regarding Preemption, the parties agreed to the redaction of email addresses, phone numbers and shipping account numbers and informed the Court of that agreement on July 25, 2017. The redactions on the documents identified on Exhibit "A" are the reflecting those agreed redactions. No substantive information was redacted.

5. During the numerous meet-and-confer sessions regarding Bard's Motion to Seal documents filed in support of Bard's Motion for Summary regarding Preemption, the parties agreed to the redactions on Exhibit "A" to the Declaration of Robert Carr. Those redactions are information that was redacted when the same documents were produced by FDA in response to a FOIA request. I was responsible for supervising the redaction process. Bard did not make any further redactions to those documents other than the ones made by FDA.

6. The redacted information in the documents identified on Exhibit "B" contains patient and medical information on patients involved in a clinical study. Plaintiffs have taken the position in this litigation that this type of information is protected.

7. Bard has now filed the documents filed in support of its Motion for Summary Judgment Regarding Preemption. The only exception is the documents identified on Exhibit "C." During the meet and confer process, Bard learned that those documents were produced by FDA pursuant to a FOIA request, but were not properly

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redacted when produced by FDA. Our office contacted both FDA and FOIA, and the redaction error was confirmed. Bard has made a new FOIA request for the documents. I informed Plaintiffs' counsel of this, and we jointly informed the Court on July 25, 2017 that the parties agree that those documents will remain under seal until Bard receives the response to the FOIA request and can redact the documents as they are redacted by FDA.

Executed on this 28th day of August, 2017.

Elizabeth C. Helm

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Exhibit A

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Documents containing agreed redactions only

A. Exhibits to Exhibit A Declaration of Robert Carr In Support of Defendants' Motion for Summary Judgment Regarding Preemption.

Ex. No.	Date	Bates No.	Description
20.	07/23/2003	BPV-17-01-00054109 through 54110	Letter BPV to FDA re Recovery Retrievable (K031328)
24.	09/17/2004	BPV-17-01-00097745 through 97746	FDA Contact Report re Recovery IFU and DDL
32.	01/10/2005	BPV-17-01-00043382 through 43402	Conference FDA and BPV re DDL and Recovery Retrievable (K031328)
53.	05/27/2005	BPVE-01-00034167 through 34168	Conference FDA and BPV re Modified Recovery (K050558)
73.	10/03/2005	BPV-17-01-00122845 through 122932	Letter BPV to FDA re G2 Everest Study (G051034) and Conditional Approval
76.	12/02/2005	BPV-17-01-00123040 through 123067	Letter BPV to FDA re G2 Everest Study (G051304) Notice of IDE Change
77.	06/21/2006	BPV-17-01-00123153 through 123175	Letter BPV to FDA re G2 Everest Study (G051304) IDE Supplement
81.	12/08/2006	BPV-17-01-00123233 through 123249	Letter BPV to FDA re G2 Everest Study (G051304) IDE Supplement
93.	10/14/2005	BPV-17-01-00125804 through 125805	Email FDA to BPV re G2 Filter - Jugular Subclavian Delivery Kit (K052578)
116.	09/04/2008	BPV-17-01-00131294 through 131295	Email FDA to BPV re FDA AI Demand re G2X (K082305)

B. Exhibits to Exhibit B Declaration of John D. Van Vleet In Support of Defendants' Motion for Summary Judgment Regarding Preemption.

Ex. No.	Date	Bates No.	Description
28.	06/27/2011	BPVEFILTER-01-01156092 through 1156185	Email from custodial file of Joni Creal with Appendix 14 Part A
29.	06/27/2011	BPVEFILTER-35-00027113 through 27173	Email from custodial file of Joni Creal with Appendix 14 Part B

Exhibit B

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Documents Containing Patient Information

A. Exhibits to Exhibit A Declaration of Robert Carr In Support of Defendants' Motion for Summary Judgment Regarding Preemption.

Ex. No.	Date	Bates No.	Description
78.	06/21/2006	BPV-17-01-00123183 through 123210	Letter BPV to FDA re G2 Everest Study (G051304)
82.	02/02/2007	BPV-17-01-00123269 through 123351	Letter BPV to FDA re G2 Everest Study (G051304) Annual Progress Report
83.	08/23/2007	BPV-17-01-00123427 through 123474	Letter BPV to FDA re G2 Everest Study (G051304) Annual Progress Report

Exhibit C

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Documents to Remain Under Seal

A. Exhibits to Exhibit B Declaration of John D. Van Vleet In Support of Defendants' Motion for Summary Judgment Regarding Preemption.

Ex. No.	Date	Bates No.	Description
37.	08/14/2009	BPV-17-01-00171823 through 171824	FDA Contact Report (Eclipse and Platinum Pre IDE)
38.	03/19/2010	BPVEFILTER-01-01138499 through 1138571	Email to FDA enclosing Denali Pre-IDE
40.	05/05/2010	BPV-17-01-00171868 through 171871	(Denali Pre IDE)
41.	05/13/2010	BPVEFILTER-01-01110191 through 1110196	Email and meeting minutes re Denali Pre-IDE
42.	05/20/2010	BPV-17-01-00171865 through 171867	(Denali Pre IDE)
46.	02/01/2011	BPVEFILTER-01-00367553 through 367563	FDA Conditional Approval of IDE with 31 questions
48.	02/16/2011	BPV-17-01-00230270 through 230281	BPV IDE Supplement #1
49.	02/16/2011	BPV-17-01-00230123 through 230269	BPV IDE Supplement #1 appendices
52.	03/16/2011	BPVEFILTER-01-01141999 through 1142002	Email confirming FDA re biocompatibility
53.	03/17/2011	BPV-17-01-00231740 through 231741	FDA letter with conditional approval of IDE
56.	09/09/2011	BPV-17-01-00231734 through 231736	FDA letter conditional approval of IDE
58.	11/03/2011	BPVEFILTER-01-01153526 through 1153528	Letter from FDA requesting more info
60.	01/31/2012	BPV-17-01-00230629 through 230644	IDE Annual Report
61.	11/13/2012	BPV-17-01-00230655 through 230749	BPV 13th IDE Supplement.
62.	12/04/2012	BPVEFILTER-01-01170973 through 1170977	Email and attachment to FDA responding to informal questions
63.	12/14/2012	BPV-17-01-00231742 through 231746	FDA Letter approving IDE change.

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Ex. No.	Date	Bates No.	Description
64.	01/10/2013	BPV-17-01-00230832 through 230904	BPV Annual IDE Report.
65.	02/07/2013	BPV-17-01-00231737 through 231739	FDA Letter with questions re IDE annual report
67.	03/01/2013	BPV-17-01-00230755 through 230831	BPV response to FDA questions re annual IDE report
68.	03/14/2013	BPV-17-01-00230014 through 230021	Emails with FDA re Denali 510(k)
69.	04/06/2013	BPV-17-01-00229495 through 229498	Email from FDA requesting additional information
70.	04/15/2013	BPV-17-01-00229652 through 229767	Email to FDA responding to questions
71.	04/15/2013	BPV-17-01-00229894 through 229998	Email to FDA responding to questions
72.	04/24/2013	BPV-17-01-00229624 through 229651	Email to FDA responding to questions
73.	05/06/2013	BPV-17-01-00229784 through 229799	Email to FDA responding to questions
74.	05/06/2013	BPV-17-01-00229537 through 229613	Email to FDA responding to questions
75.	05/08/2013	BPV-17-01-00229823 through 229838	Email to FDA with redlined IFU
76.	05/10/2013	BPV-17-01-00229493 through 229494	FDA email to BPV re revised IFU
77.	05/10/2013	BPV-17-01-00229854 through 229868	Email to FDA with revised 510(k) summary
80.	01/30/2014	BPV-17-01-00230921 through 230999	BPV IDE Annual Report
81.	11/07/2014	BPV-17-01-00217322 through 217528	Denali Special 510(k) (K143208)
83.	01/30/2015	BPV-17-01-00231017 through 231170	BPV Annual IDE Report
84.	01/29/2016	BPV-17-01-00231188 through 231623	BPV IDE Final Annual Report
85.	02/16/2016	BPV-17-01-00231748 through 231749	FDA email re final IDE and annual report
86.	02/18/2016	BPV-17-01-00231751 through 231756	BPV email responding to questions of Feb. 16
87.	02/26/2016	BPV-17-01-00231750	FDA letter closing Denali IDE